

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

CAROL LEWIS,	)	
	)	
Plaintiff,	)	Civil Action No.:
	)	1:15-CV-13530-NMG
v.	)	
	)	
DON WRIGHT,	)	Leave to file granted 11/1/2017
Acting Secretary of Health and Human	)	
Services,	)	
	)	
Defendant.	)	
	)	
	)	

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**DEFENDANT'S SURREPLY TO PLAINTIFF'S REPLY ON MOOTNESS  
AND HER FILING OF "SUBSEQUENT AUTHORITY"**

**A. Plaintiff's Reply on Mootness.**

Plaintiff's Reply on Mootness does not assist her Motion to Alter or Amend Judgment. She first takes the position that this action is not moot because the case "is the result of the Secretary's refusal to pay \$2,842 for coverage for Ms. Lewis' Medtronic CGM for the months of June 2011 and March, June, September, and November 2012," and that her Complaint seeks to recover this sum in damages. This information and prayer for relief is not in her Complaint, and adding it here does not alter the nature of the Complaint, which seeks declaratory relief.

Plaintiff's Reply then takes the position that Plaintiff is entitled to application of the "voluntary cessation" exception to the mootness doctrine. This doctrine provides that a Court may assume jurisdiction to rule on a practice of a defendant's that is no longer occurring but is "in duration too short to be fully litigated prior to its cessation. . ." and "there was a reasonable expectation that the same complaining party would be subjected to the same action again." That

is, that the issues are “capable of repetition, yet evading review.” *See* Defendant’s Reply to Plaintiff’s Motion to Alter or Amend Judgment at 7; *see Davidson v. Howe*, 749 F.3d 21, 26 (1<sup>st</sup> Cir. 2014). However, the voluntary cessation exception is inapplicable to this action. The purpose of the voluntary cessation exception is prevent a defendant from “evad[ing] judicial review, . . . by temporarily altering questionable behavior.” *See* Defendant’s Reply at 6, *citing City News & Novelty, Inc. v. City of Waukesha*, 531 U.S. 278 (2001). It is Plaintiff’s actions that have changed; Plaintiff is no longer using the device that she sued upon, the Medtronic CGM, and has decided to use the Dexcom CGM instead. Defendant has never altered its policy. Its policy of refusing Medicare coverage for the Medtronic CGM is steadfast; Defendant could not have altered its policy temporarily to evade judicial review, and the “voluntary cessation” exception is inapplicable.

Plaintiff takes the position that the burden is on the Defendant to show that the “voluntary cessation” doctrine does not apply. Plaintiff’s Reply at 4. Defendant, of course, meets that burden; but it points out that the burden is, in fact, upon a plaintiff to establish the application of this exception. *Davidson v. Howe*, 749 F.3d at 26; *ACLU v. Conference of Catholic Bishops*, 705 F.3d 44, 57 (1<sup>st</sup> Cir. 2013) and cites therein; *Cruz v. Farquharson*, 252 F.3d 530, 535 (1<sup>st</sup> Cir. 2001).

Plaintiff takes the position that this action is not moot because sometime in the future, Medicare may deny coverage of the Dexcom CGM that Plaintiff is currently using. Such an action by Medicare would of course be subject to agency administrative appeals and judicial review. It is not the subject of this action. In any event, for the record, the evidence that Plaintiff offers regarding her speculation that Medicare might sometime in the future deny coverage of her Dexcom CG is irrelevant to Plaintiff’s argument. Plaintiff appears to contend

that her Dexcom CGM is at peril because Medicare denied coverage of a Dexcom CGM to another Medicare beneficiary, an unnamed individual in Oregon. The Medicare Summary Notice included in Plaintiff's Exhibit A as to that unnamed Medicare beneficiary indicates that that claims for CGM coverage used the wrong billing codes.<sup>1</sup> And that Medicare coverage decision was made in a different state and processed by a Medicare administrative contractor who lacks authority to make decisions on Plaintiff's coverage. Exhibit A does not indicate whether the unnamed Medicare beneficiary sought coverage for the same device that Plaintiff uses, the Dexcom G5, or, rather, for a different Dexcom CGM that is not approved by the FDA and not covered by CMS Ruling No. 1682-R. Nor does it indicate that the unnamed beneficiary had demonstrated a reasonable and necessary need for a Dexcom CGM, an element of the standard for Medicare coverage. *See* 42 U.S.C. § 1395y(a)(1)(A); Def. Reply to Pl.'s Motion to Alter or Amend Judgment, at 9; Def's Memo. of Law in Support of HHS' Motion to Affirm HHS' Decision and In Opposition to Plaintiff's Mot. For Summary Judgment at 3. Accordingly, Plaintiff's reference to the unnamed Medicare beneficiary sheds no light on Plaintiff speculation that her Medicare coverage of her Dexcom CGM might be some time in the future be terminated, even if Plaintiff's speculation were relevant to mootness, which it is not.

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<sup>1</sup> The transmitter was submitted under billing code A9277-GY, the receiver was submitted under billing code A9278-GY, and the sensors were submitted under A9276-GY. However, CMS guidance made clear that claims for CGM transmitters, receivers, and sensors for dates of service between January 12, 2017 and June 30, 2017 should be submitted under billing codes E1399 and A999. *Coding and Coverage – Therapeutic Continuous Glucose Monitors (CGM)*, <https://www.cgsmedicare.com/jb/pubs/news/2017/03/cope2581.html> (Mar. 23, 2017); *Continuous Glucose Monitors – Frequently Asked Questions*, <https://www.cgsmedicare.com/jc/pubs/news/2017/0517/cope3049.html> (May 4, 2017) (noting that new billing codes specific to therapeutic CGMs have been established at K0553 and K0554 but claims with dates of service between January 12, 2017 and June 30, 2017 should still use the previously identified codes E1399 and A999).

**B. The “Subsequent Authority” Submitted by Plaintiff is Irrelevant to her Motion**

In her most recent filing, Plaintiff submits a decision from the United States District Court, Eastern District of Wisconsin, ruling on Medicare coverage of a CGM manufactured by Medtronic. This decision is irrelevant to Plaintiff’s Motion to Alter or Amend Judgment, since the Court’s decision is grounded in mootness and makes no judgment on whether Defendant was within its discretion in denying coverage of Plaintiff’s former, Medtronic CGM.

For the reasons set forth herein and in Defendant’s Reply to Plaintiff’s Motion to Alter or Amend Judgment, Defendant requests that the Court deny Plaintiff’s Motion to Alter or Amend Judgment.

Respectfully submitted,

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Certificate of Service

I hereby certify that the foregoing will be filed through the electronic filing system of the Court, which system will serve counsel for Plaintiff electronically, on this first day of October 2017.

/s/ Anita Johnson \_\_\_\_\_